

WHEN SIX-SIGMA ISN'T GOOD ENOUGH

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The recent focus on six-sigma processes in high consequence industries is a significant and positive development. We must distinguish between its powerful contribution to process health yet be mindful of where 'six-sigma' is inadequate as a measure for high volume, complex systems. We must also realize that as highly appropriate as it is to process management it fails us in addressing issues of human factors. Larger, systemic solutions are required. This paper presents a model of learning progression in systems thinking and a model to ensure the right information is gathered, analyzed and acted upon to create outstanding safety performance across industries.

All high consequence industries seem to get a wake up call in terms of safety. The causes vary, but typically it is a major catastrophe or sequence of severe events that get the headlines. This is typically true, but not always the case. Regardless of when an industry receives their wake up call, there are strategies to increase safety that can be applied across industries now.

Many published works in recent years have focused on specific techniques that address safety in particular industries. One such example is a well written article about the use of failure mode effect analysis, or FMEA, a standard six-sigma technique to reduce medical errors (Reiling et al, 2003). There is ample evidence that a six-sigma approach, or many other team-based or process-based approaches pays safety dividends for those organizations that commit to using them. However although these programs provide solid benefits, they alone fail to meet the most powerful need – that of systemic change.

My experience in two high consequence industries (construction, aviation) and in consultation with two others (medical, utility) has shown me that the same mistakes are being made across industries, albeit with different results. I find little evidence that people within an industry believe that the experiences elsewhere can be of benefit to them. I propose that it is not the specific intelligence gained from safety studies in these industries that is powerful, it is the framework and methods within which investigators arrive at their conclusion and disseminate intelligence that is entirely transferable.

What is Six-Sigma?

Much has been written about six-sigma in the business press and if you dig deeply into statistical theory you will find more academic explanations of the subject. For the benefit of this paper I will simplify it into a single statement – six-sigma is 3.4 errors per million opportunities. That is 99.997% excellence. If you're processing checks in a bank, six-sigma is not a bad target – and nobody gets hurt by a mis-processed check. But what about the delivery of acute care in a hospital, operating nuclear reactors in power plants that neighbor communities, hurtling passengers down railway lines at over 150 mph or flying 400 people around the country?

To illustrate what six-sigma means, consider the day-to-day events at Southwest Airlines. Southwest (SWA, 2003) flies around 2,700 flights a day. Assume their average load factor is 100 people per flight. Landing and take-off are the two most failure prone segments of a flight. If we consider only these two aspects of flight, Southwest has 540,000 opportunities for a passenger injury each day. (2700 x 2 x 100). Six-sigma means 'only' 1.8 passenger injuries occur each day. In fact, Southwest has operated for over 30 years without a major accident and has experienced very few passenger injuries of any significance.

There are other industries that already achieve and exceed the six-sigma standard. If we can hit or exceed six-sigma, why are we still worried about safety? The answer is the cost of the loss, in terms of human suffering, reputation and money.

I suggest that counting errors the way businesses count defects in six-sigma programs can lead to a false sense of security in problem solving in high consequence industries. A common method to count defects however is valuable for comparative purposes.

I decided to test this suggestion by researching articles and interviewing experts about specific improvement techniques and philosophical safety modes. I then linked the results to my own experiences, notes and data. I concluded that we will get much better safety results if we focus on the operational processes that lead to error and the systemic processes within which we learn, rather than by using arbitrary measures or single techniques.

Systems Thinking

In his landmark research and book (Senge, 1990) Peter Senge teaches us the concept of a balanced system and the effect of an interruption to that system. This is a much harder concept to get across than six-sigma, but it offers a truly remarkable perspective on solving systemic process problems and I believe it holds the key to industry transferability of techniques. We have to learn to distinguish between the disrupter and the deadly consequence versus the innocuous procedural

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sequence. Senge suggests that we are victims of our own thinking – in fact we have a balanced perspective of an imbalanced system. My research and experience tells me this is true and I concluded that we must provide a new overall framework or system before we can tie together all the efforts underway in safety management.

Senge provided us, at the time with insight beyond our capability to use it. Over time, those who have followed his thinking, or who have toyed with his ideas have a deeper understanding of what creates systemic change. On the whole, systemic change is good, it is rarely won by revolution, more frequently by evolution and the insight from it is enduring. What does this tell us about safety?

First, resistance is a natural process. We often hear about human resistance to change but nature resists change. It fights it until it becomes life threatening and then it adapts. Humans do no more or less than nature itself. If we address resistance as a natural phenomenon in safety programs we will get more realistic results. I found very few people who didn't 'care' about safety when asked directly, but when I asked them how they would react to being asked to behave differently to achieve a safer environment I received a different response. Questioning my own reality, when I'm not focused on safety analysis, I found I too do the same. However I received the same results regardless of the industry of the people I was interviewing.

Second, resistance can be overcome. Convincing forces exist to reduce resistance to change and allow a new reality to occur. The forces are to some extent natural – for example the general belief that safety (or fear of accident) is goodness and that a drift toward safety is better. Some forces are manufactured, such as incentives to reward safety, programs to make safety a conscious element, or the negative consequences of not following the topic carefully – for example, lawsuits, public humiliation, worker compensation programs etc.. Again, these issues were faced in all industries I researched.

Third, the new reality becomes the 'established' system, subject to new change stresses. Over time, our original collective attitude toward safety normalizes around new standards and we become comfortable and satisfied with the system around us, only for a disrupter to start the change cycle again. No difference was found between any of the industries I studied.

System Frameworks

Armed with the insight of Senge and knowing the cost of failure in high consequence industries, we need to examine the frameworks that constitute our current systems. There are some systemic frameworks in existence that shed light on our path. The most successful industrial model in my

experience is the Aviation Safety Reporting System (ASRS) developed for the Federal Aviation Administration. Much has been written about this system and how it has contributed to aviation safety over the years. Recent statistics show that the ASRS receives about 30,000 entries annually (IOM, 2000). The JCAHO database had received 194 entries in 5 years of recording (Moore 1998). The same text states that the FDA receives approximately 235,000 reports annually for drug events and about a third that number on device problems. Elements of each of these systems encourage, discourage or enforce reporting. Motivation is the essential element that determines the effectiveness of a safety system.

The Industrial Model

I evaluated what impact different industrial models had on safety programs. I researched experiences in transferring aviation safety practices to the medical profession in the US and the UK. The airline industries of these two countries are structured similarly, although the UK is subject to more international flying.

The medical industries are fundamentally different due to the private practice model of the US and the public infrastructure of the National Health Service in the UK.

The airline industries have similar models. In the UK, British Airways created the first successful model called the Special Event Search and Master Analysis (SESMA) to record flight data and anonymously track aircraft handling outside the design envelope. (O'Leary, 2002). That was followed by the Air Safety Reporting (ASR) program and has progressed to add a human factors reporting (HFR) element. In the US, the Aviation Safety Reporting System performs the function of the first two UK systems. Both models are well used today and have contributed greatly to safety. Both models were slow to be adopted at first. Both models initially met with resistance from pilots and from other staff as the programs reach grew. There was no similar comparison between the US and UK in health care.

I expected that the 'corporate' nature of the UK doctor with their NHS relationship would result in a quicker acceptance of safety related change. This turned out to be a false assumption as the reaction of doctors to reporting systems was no different from the UK to the US. The NHS is working with the UK airline industry to find solutions (Svatek, 2003). I also expected that rigorous NHS standards would have already reduced the number of medical errors. I was unable to find clear comparative data that would prove or disprove this assumption. The only enforced standards I found related to patient encounter reporting and national insurance payment procedures. My third expectation was that of a quicker rate of best practice knowledge transfer under the NHS umbrella. Anecdotally, this turned out to be partially

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valid, but the impact it had on surgical procedures was minimal and there is no definitive data. An operating room simulator was created by a technical specialist who had significant experience developing flight simulators (unpublished). Five UK surgeons were invited to perform the same surgical procedure on the simulator. The purpose was to observe the surgeons so that better simulators could be developed. Each of the five surgeons performed the procedure a different way. Only two were found to operate in a similar sequence.

In the US, the medical profession has been described as having a craft model “founded on assumptions that were once arguably valid but no longer apply.” (Merry, et al, 2001). Care is provided primarily from individual practitioners. Even when these practitioners get together and form a medical group for mutual support and reduced administrative and facility cost, they still operate and deliver as individuals. The individual practitioner ability grows with their own experience and to the extent they communicate among those they choose to associate with professionally. Professional bodies such as the American Medical Association (AMA) are the primary sources of ongoing learning about new and improved techniques, supplemented by newsletters or bulletins from their own medical groups or hospitals.

In the UK, the same system is in operation. Doctors and surgeons, once they qualify from medical school and internships practice as individuals and learn of each others work through personal contacts and through publications and functions of professional bodies such as the British Medical Association (BMA).

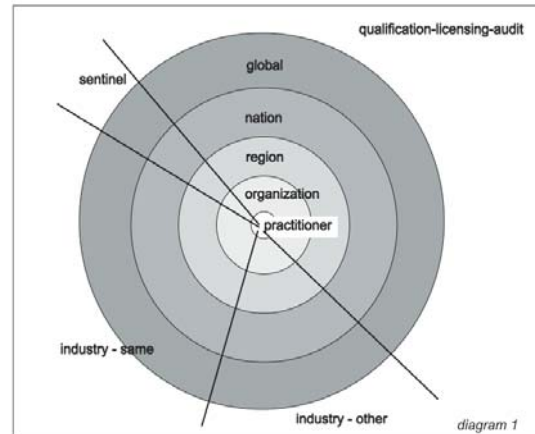
Despite the structural similarities and differences I found that there are cultural, professional and organizational similarities between the aviation and medical industries to make valid comparisons. Resistance to change appeared to take exactly the same form, regardless of systemic differences.

Systemic Model

I created a model, outlined in diagram 1, to help clarify the fundamental domains that must be aligned to create an effective safety culture within any industry.

The topic is complex. In my research I see thousands of arguments and counter arguments, each one of which has some merit. In fact I list a number references in the general references below that hold an opposing view to my own. I found a large quantity of writing that addresses the safety issue emotionally. Such writing makes compelling argument for improving safety and touches on the sensitivities of humans operating within a high-consequence system but offers little in the way of solutions.

I use this model to help frame arguments that lead to solutions.

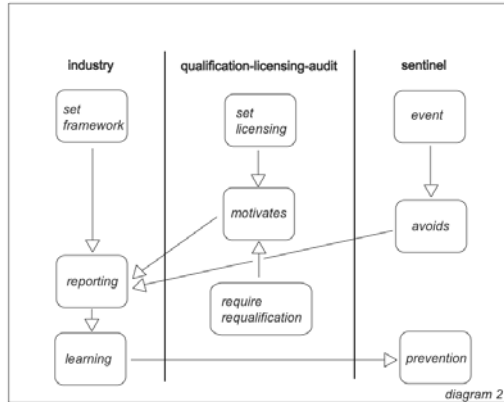


The model demonstrates the global system under which a particular industry operates its safety efforts. The primary domains are professional, organizational and regional. The practitioner is always at the center – the surgeon, pilot, nuclear reactor operator. They operate within an organization that can vary from a sole proprietorship to a major corporation. The organization exists within any number of geographical boundaries which I will represent as the regional and national boundaries. In almost all cases today, the industries operate in a global marketplace (employees, customers, training sources, regulations etc). An overall safety model must address and satisfy needs in each of the concentric rings but also integrate across the rings so there is a clear line from the practitioner to global results.

Superimposed on the concentric model are secondary domains that cross the rings – qualification-licensing-audit; a sentinel event; safety learning (within the industry and across industries).

I break the superimposed domains into the secondary model in diagram 2 to show the different motivations a safety solution must address.

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The qualification-licensing-audit domain represents the motivations of those interested in setting and maintaining a particular standard. These are usually highly specialized individuals who approach the issue from logical set of tests, measures and observations.

The industry domain (within and across industries) represents the most likely domain of continuous learning, understanding, sharing and improvement. It mixes the data from the qualification-licensing-audit domain with supplemental information and analysis and offers safety solutions in a non-threatening manner.

The sentinel event domain represents the highly emotional domain of injured parties, families, politicians, embarrassed practitioners, public reactions and calls for 'immediate action'. This is the domain that lawyers operate in. They will however build cases with all the information they have the right to access across any of the three domains.

To create effective safety systems the elements of the system must be understood. This will allow consensus decisions on the most appropriate safety programs to fit each element of each domain.

Primary Domains

The practitioner has an obligation to be fully trained for the profession, to maintain the level of skill and improve and expand that skill over time. They have a personal sense of the need for safety which includes the safety of those they work with. They are aware of the personal liability for failure. Their learning sphere contains what they experience, what they hear from colleagues, published professional material and additional training. They make a personal choice to participate in safety learning.

The organization has institutional obligations to operate in a safe manner. It addresses an almost universally unspoken customer expectation for absolute safety – it is expected, nothing less is acceptable. The organization is aware of its liability for failure. The organization has the benefit of

aggregating data among its members and if it chooses it can disseminate that data back to its members for improvement. If the data is analyzed and recommendations are offered, the benefit is enhanced. The organization can require a level of compliance to safety programs from its members. It can set up voluntary or compulsory participation with safety programs.

Regional and national bodies have an obligation to protect the community at large. They have a policy driven system that establishes standards and installs methods to determine adherence to those standards. They require remedial action if standards are not met. They create penalties for unsafe practices or results. They set qualification, re-qualification and continual learning standards, in some cases.

Regions also have a large constituent base from which to collect data and use it to identify trends and prepare recommendations. They set up voluntary and/or compulsory programs. They can retain monitoring activities or delegate them to organizations and practitioners under oversight.

The increasing value provided as you move further out across the primary domains is the expanding ability to learn from larger and larger populations of data, and the greater impact in demanding adherence to best practices. This holds true regardless of industry. Therefore, differences and disconnects between safety programs across these primary domains reduces the impact of safety learning and compliance. Our efforts should be directed toward commonality, moving to more successful models, improvement of best current models and integration between each concentric ring.

Secondary Domains

The industry domain is where people spend most of their professional time – practicing, reading and attending industry events. This is the most collegiate of the domains and the one most likely to achieve the greatest success in encouraging participation in any program. This is where people are most likely to report events fully and accurately. Therefore learning systems should be concentrated in this domain in industry or specialized segment models. Protecting data from legal discovery is most effective here and practitioners feel the least threatened and the most understood. Safety program ideas that transfer (techniques, motivations, procedures, protections, policies) should be refined within an industry and specialized segment to maximize the impact of learning.

The qualification-licensing-audit domain also cuts across the primary domains and research shows rule variation, differing licensing requirements, requalification expectations and application. This domain will provide the biggest impact on safety because it will legitimize the industrial domain

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intelligence and be the motivator for reporting in the least threatening domain.

Pilots and nuclear reactor operators for example are required to attend continual training, to understand updated procedures and to recertify. They are also observed by peers who perform an auditor role. Contrast this to the medical profession. Doctors resist the notion that peer observation in an auditor role will make a difference. Understandable resistance indeed, but research shows that pilots didn't like the idea of check rides either when they started – they still don't like them but accept them as an important pillar of the safety system. Again, Senge's fifth discipline bears out as the pilots came to a new norm.

The sentinel event domain is the most feared. It is the reason we have safety programs yet it is the least likely area where safety improvements will be made. When a sentinel event occurs, people suffer. That starts a series of processes that are typically punitive, accusatory and emotional. Rightfully, the aggrieved parties want redress – which brings out the lawyers. This severely restricts the flow of information. Nobody will give more than the minimum they can get away with. I believe it inconceivable that this will change in a significant way. Airline employees have had protection for many years for safety issues they report in the other domains, but when an aircraft is lost there is still significant liability for all involved. In analysis of the three-mile island and Chernobyl disasters, the same reaction to the sentinel event occurred (Medvedev, 1991). Effort spent in this domain trying to protect and gain exemptions from the legal process will be the hardest to address and will have little impact to the core goal – improved safety.

Conclusion

The model I have outlined provides a framework based on research for us to align our safety activities within and across industries. We can test whether information reported locally is used for organizational, regional, national and international benefit. It will only do this if practitioners agree on the goal, nature and purpose of reporting.

The existence of successful models in many industries means we are out of time discussing whether these will work in another. They do exist. If a lawyer can make a case that information was available had we chosen to use it, then we must get ahead of the sentinel event and start learning now.

We must review whether we are prisoners of our own thinking, look at the facts and act upon new models that serve all stakeholders. The solutions must fully integrate across the domains and every success must be celebrated.

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